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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,268	10/29/2003	Sang-Nyun Kim	4084-032129	6488

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/696,268

Applicant(s)

KIM ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 10-14 is/are rejected.
- 7) ☒ Claim(s) 6-9 and 15-18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 20040322.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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1. The disclosure is objected to because of the following informalities: The status of parent application 10/141,723 should be updated in the priority claim at page 1, paragraph [0001], of the specification. Appropriate correction is required.

2. Claims 2, 3, 11, and 12 are objected to because of the following informalities: In claim 2, it is probably not necessary to place brackets around the names of the possible X residues. At claim 3, line 2, the end bracket is unmatched. Appropriate correction is required.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 and 10-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,790,830. Although the conflicting claims are not identical, they are not patentably distinct from each other. The '830 patent claims a method for treating alopecia and for promoting hair growth by administering a composition comprising 3-position analogs of cyclosporin. The 3-position residue of the claimed analogs can be of General formula 2, and when x is S, then R² can be C₂ - C₆ straight or branched alkyl, alkenyl or alkynyl moieties, substituted or unsubstituted with one or more selected from the group consisting of amino, hydroxy, halo, haloalkyl, ester, alkoxy, cyano, nitro, alkylamino, and dialkylamino. The '830 patent does not specifically claim such 3-

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position analogs in which no other residue of the cyclosporin analog is altered. It would have been obvious to one of ordinary skill in the art to use such 3-position analogs in the claimed method of the '830 patent because the claims of the '830 patent generically encompass such 3-position analogs, because the preferred 3-position analogs claimed in the '830 patent do not alter any other residue of the cyclosporin, because one skilled in the art would alter the minimum number of residues possible in order to maintain the activity of the basic peptide, and because such analogs have only the hair growth promoting activity which would have been expected in view of the claims of the '830 patent.

4. The effective filing date of instant claims 1, 2, 6-11, and 15-18 is deemed to be October 29, 2003, the filing date of the instant application. Instant claims 1, 2, 6-11, and 15-18 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 10/141,723 because the parent application '723, under the test of 35 U.S.C. 112, first paragraph, does not disclose the full range of the R groups recited in instant claim 1, and does not disclose the alkylthio, benzylthio, 4-nitrophenylthio, or dimethylthiocarbamyl R groups recited in instant claims 2 and 6-9. Accordingly, because the inventorship of U.S. Patent No. 6,790,830 is different than the inventorship of the instant claims, U.S. Patent No. 6,790,830 is available as prior art against instant claims 1, 2, 6-11, and 15-18 under 35 U.S.C. 102(e). Because the inventorship of WO Patent Application 2002/92032 is different than the inventorship of the instant claims, WO Patent Application 2002/92032 is available as prior art against instant claims 1, 2, 6-11, and 15-18 under 35 U.S.C. 102(a).

The effective filing date of instant claims 3-5 and 12-14 is deemed to be May 9, 2002, the filing date of parent application 10/141,723. Instant claims 3-5 and 12-14 are deemed to be

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entitled under 35 U.S.C. 120 to the benefit of the filing date of the parent application '723 because the parent application '723, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed invention.

5. Claims 1-5 and 10-14 are directed to an invention not patentably distinct from claims 1-10 of commonly assigned U.S. Patent No. 6,790,830. Specifically, see the above obviousness-type double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. Patent No. 6,790,830, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. *Joy Technologies Inc. v. Quigg*, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In *re Hoeschele*, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In *re Clinton*, 188 USPQ 365, 367 (CCPA 1976); In *re Thompson*, 192 USPQ 275, 277 (CCPA 1976).

7. Claims 1, 2, 10, and 11 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,790,830. See the above obviousness-type double patenting rejection.

8. Claims 1, 2, 10, and 11 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 2002/92032. The WO Patent Application '032 is equivalent to U.S.

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Patent No. 6,790,830 applied above, and the WO Patent Application '032 suggests claims 1, 2, 10, and 11 for the same reasons that U.S. Patent No. 6,790,830 suggests these claims.

9. Claims 1 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Seebach (U.S. Patent No. 4,771,122). Seebach teaches the compound of Examples 24, 25, and 40, which have the same structure as Applicants' Formula 1. Specifically, these three examples have groups which correspond to Applicants' R which is cyclic or aryl, cyclic or aryl, and a C₂ alkyl substituted with an ester, respectively. Seebach also teaches compounds having groups which correspond to Applicants' R which is 2-hydroxyethylthio or 2-methoxyethylthio. The compounds of Seebach are used pharmaceutically, e.g., in combination with a liquid pharmaceutical diluent or carrier. See, e.g., column 5, lines 35-43, and column 23, lines 61-62. With respect to the phrase "hair growth promoting" in the instant claims, an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated by the prior art. Alternatively, in view of the identity in structure between Seebach's cyclosporin analogs and Applicants' claimed agent, inherently the former will have hair growth promoting activity to the same extent claimed by Applicants.

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Viskov (U.S. Patent Application Publication 2001/0025025). Viskov teaches cyclosporin analogs in which the residue at position 3 has a structure which satisfies Applicants' General formula 1 in which R is General formula 2 in which X is sulfur and R' is a substituted C₂-C₄ alkyl group. The analogs are to be used therapeutically. See, e.g., paragraphs [0127] through [0132], and Examples 2 and 4.

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11. Claim 10 is rejected under 35 U.S.C. 103(a) as being obvious over Viskov (U.S. Patent Application Publication 2001/0025025). Application of Viskov is the same as in the above rejection of claim 1. Viskov does not teach its cyclosporin analogs in the forms recited in instant claim 10. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to formulate the cyclosporin analogs of Viskov in the forms recited in instant claim 10, because it is conventional to formulate therapeutic agents in such forms for ease of storage, transport, measurement, and administration, and because cyclosporin is commonly administered in such forms, especially as a liquid formulation or as an emulsion.

12. Claims 6-9 and 15-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art of record does not teach or suggest cyclosporin analogs having the structures recited in instant claims 6-9. Accordingly, compositions comprising the analogs are also novel and unobvious over the prior art of record, as would be claims directed to methods of using the analogs.

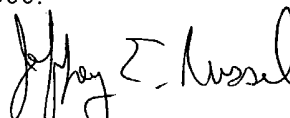
Kim et al (U.S. Patent No. 6,762,164) is cited as art of interest, but its claims are not deemed to raise any issues of obviousness-type double patenting with the instant claims. For prior art purposes, Kim et al '164 is duplicative of U.S. Patent No. 6,790,830 applied above.

Barrierre et al (U.S. Patent No. 5,965,527) is cited as art of interest, being essentially duplicative of the references applied above.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

December 7, 2004